IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. APOTEX INC., and APOTEX CORP., Defendants.	C.A. No.: 07-809-JJF-LPS **REDACTED VERSION DI 39**

PLAINTIFFS' OPPOSITION TO DEFENDANT APOTEX INC.'S RULE 12(b)(2) MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION, OR IN THE ALTERNATIVE TO TRANSFER TO THE MIDDLE DISTRICT OF FLORIDA

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Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, "AstraZeneca") oppose the motion of Apotex Inc. to dismiss the Complaint against it for alleged lack of personal jurisdiction for the reasons set forth below.

I. THE NATURE AND STAGE OF THE PROCEEDINGS

This is an action for infringement of U.S. Reissue Patent RE 37,314 ("the '314 patent") covering the active ingredient (rosuvastatin calcium) in AstraZeneca's blockbuster cholesterol-lowering pharmaceutical Crestor®. The action results from the filing by Defendant Apotex Inc. through its agent and sister company, Defendant Apotex Corp., of an Abbreviated New Drug Application ("ANDA") to market a generic version of Crestor® tablets. Apotex Inc. notified AstraZeneca that Apotex Inc. had filed an ANDA with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) with a "Paragraph IV" certification that it intended to market its generic drug in the United States prior to expiration of the '314 patent. (AZ Ex. 1 at 2.)

That was one of nine Paragraph IV notifications received by AstraZeneca between October and December 2007 relating to proposed generic versions of Crestor® tablets. To seek resolution of the multiple challenges to its patent rights, AstraZeneca filed seven related patent infringement actions in this district on December 11, 2007. (C.A. Nos. 07-805, 07-806, 07-807, 07-808, 07-809, 07-810, and 07-811.)[1]

[1] AstraZeneca sued seven of the nine for infringement of the patent covering the active ingredient in Crestor® tablets—the '314 patent. Two of the Paragraph IV certifiers did not challenge the '314 patent with Paragraph IV certifications.

Five sets of the defendants answered the Complaints, while Apotex Inc. and Apotex Corp., and Defendants Aurobindo Pharma Limited and its subsidiary Aurobindo USA, did not. Apotex Inc. and Aurobindo Pharma Limited challenged personal jurisdiction in Delaware. Apotex Corp. and Aurobindo USA, however, did not challenge personal jurisdiction, apparently since each is a Delaware corporation. Apotex Corp. and Aurobindo USA, however, challenged subject matter jurisdiction. The parties agreed to limited jurisdictional discovery to develop the factual record.

This brief opposes Apotex Inc.'s motion to dismiss for alleged lack of personal jurisdiction. In its separate brief, AstraZeneca opposes the Aurobindo defendants' motion to dismiss for alleged lack of personal jurisdiction and nonjoinder. The defendants' motions to dismiss for alleged lack of subject matter jurisdiction already have been fully briefed.

II. SUMMARY OF THE ARGUMENT

Personal jurisdiction over Apotex Inc. is proper in Delaware. Without qualification, Apotex Inc. admitted personal jurisdiction in another ANDA patent infringement case in this district, and repeatedly consented to personal jurisdiction in seven others. It even consented in another case after filing its present motion. But even setting aside that admission and those concessions, Apotex Inc. maintains systematic and continuous contacts with Delaware in at least two ways. First, because of the very nature of its business model and the United States' statutory scheme enabling all generic drug companies to obtain FDA approval to market generic copies of branded drugs, Apotex Inc. conducts its regular and ordinary business of litigating patents instigated by its ANDA filings—including in particular nine other litigations in Delaware in the last five years—to gain access to the U.S. marketplace, including Delaware, for those drug products. Second, Apotex Inc. markets, distributes, and sells its generic drugs in Delaware and the rest of the United States through its agent and corporate sister, Apotex Corp., which is a

Delaware corporation.

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Finally, Apotex Inc.'s proposed sales of infringing drugs will considerably injure a Delaware citizen having its headquarters in Wilmington, Delaware—AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharmaceuticals"). Accordingly, the exercise of personal jurisdiction over Apotex Inc. is proper and meets the requirements of due process.

III. STATEMENT OF FACTS

A. AstraZeneca and Its Relation to Delaware

Plaintiff AstraZeneca Pharmaceuticals has its headquarters in Wilmington, Delaware, and employs thousands of people in Delaware. (AZ Ex. 2 at 2.) It is the authorized agent for matters related to NDA No. 021366, for Crestor® pharmaceuticals. (D.I. 1.1 ¶ 8.)[2] AstraZeneca Pharmaceuticals and its related companies manufacture, market, and conduct research and development on, *inter alia*, its Crestor® pharmaceuticals. (*Id.* ¶ 10.) Crestor® is a prescription pharmaceutical that is used to treat high cholesterol and is one of the most effective lipid-lowering statins available. (*Id.* ¶ 9.) Over 11 million patients have been prescribed Crestor® pharmaceuticals, and over 110 million prescriptions have been written worldwide for those pharmaceuticals. (*Id.*) AstraZeneca Pharmaceuticals and its related companies financially benefit from sales of Crestor® tablets in the United States, including Delaware. (*Id.* ¶ 10.)

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[2] In considering a motion to dismiss under Rule 12(b)(2), "all allegations of jurisdictional fact made by a plaintiff are presumed to be true and all factual disputes are resolved in plaintiff's favor." *Jeffreys v. Exten*, 784 F. Supp. 146, 151 (D. Del. 1992).

B. Apotex Inc. and Its Involvement in the U.S. Generic Drug Market

Apotex Inc. is a Canadian company that manufactures and sells generic drugs worldwide through its Apotex Group of companies. (AZ Ex. 3 at 3.) According to its website, Apotex Inc. is now "the largest Canadian-owned pharmaceutical company," and "has grown to employ over 6,500 people in research, development, manufacturing and distribution facilities world-wide." (*Id.*) From its start, Apotex Inc. was set up to manufacture generic drugs for export into the United States: "The Etobicoke [Canada] Site of Apotex was established in June of 1993 . . . to serve as the manufacturing arm of an effort to enter into the U.S. oral solid dosage market, namely tablets and capsules, for Apotex Inc." (*Id.* at 2.) Even today, "Apotex Etobicoke, located in Etobicoke, Ontario, manufactures most U.S. tablet and capsule pharmaceutical products, and Apotex Richmond Hill, located in Richmond Hill, Ontario, manufactures and packages liquids, aerosols, ophthalmics, injectables, form-fill and seal unit dose packaging." (*Id.* at 7.)

Apotex Inc. holds itself out as the head of the global Apotex Group. (*Id.* at 4-5.) The Apotex Group acts as one in support of its common goal, as its website explains: "As Canada's largest pharmaceutical company, the Apotex Group of Companies together research, develop, manufacture, and market close to 300 generic pharmaceutical products for the Canadian market and around the world." (*Id.* at 2.)

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Accordingly, Apotex Inc. has repeatedly admitted in litigations in this district that it has manufactured numerous drug products that are sold and used in Delaware.[4]

C. Apotex Inc.'s Litigation Business in Delaware

A *generic* drug company's need to litigate patents covering FDA-approved branded drug products is an inextricably intertwined feature of its business model. Considering the rights, requirements, and procedures of the Hatch-Waxman Act, including all its vagaries and enabling regulations, generic drug companies, like Apotex Inc., exist in large part to litigate patents. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002) (explaining Hatch-Waxman Act scheme); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1325-27 (Fed. Cir. 2001) (same).

Over the last five years, in Delaware alone, Apotex Inc. has been a party to nine other ANDA-related patent suits. (AZ Ex. 5 at 6-8.) In one, Apotex Inc. was a plaintiff in a declaratory judgment suit. (AZ Ex. 6.) In seven of the remaining Delaware cases (the eighth was dismissed before the Answer was filed), Apotex Inc. answered the Complaint, raised

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[4] AZ Ex. 7 (Apotex Inc. Answer to sanofi-aventis Complaint) at ¶3 (admitted that "Apotex Inc. manufactures numerous drugs that are sold and used in [Delaware]"); AZ Ex. 8 (Apotex Inc. Answer to Senju Complaint) at ¶8 (admitted that "Apotex Inc. manufactures numerous drug products for sale and use in the United States including [Delaware]"); AZ Ex. 9 (Apotex Inc. Answer to Allergan Complaint) at ¶4 (admitted that "Apotex, Inc. [sic] manufactures numerous generic drugs for sale and use throughout the United States, including [Delaware]"); AZ Ex. 10 (Apotex Inc. Answer to MedPointe 2007 Complaint) at ¶3 (admitted that "Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in [Delaware]"); AZ Ex. 11 (Apotex Inc. Answer to Medpointe 2006 Complaint) at ¶3 (admitted that "Apotex Inc. manufactures generic drug products that are approved by the [FDA] and that the approved drug products are sold in the United States.").

Counterclaims, and never challenged personal jurisdiction. (AZ Ex. 5 at 6-8; AZ Exs. 7 - 13 (Answers to Delaware Complaints).) Moreover, in February of this year, after filing its present motion contesting this Court's jurisdiction over it, Apotex Inc. nevertheless again consented to personal jurisdiction in this district. (AZ Ex. 12.) In addition, less than a year ago, Apotex Inc. unequivocally admitted in another ANDA patent case that personal jurisdiction over it was proper in this district. (AZ Ex. 9 (Apotex Inc. Answer to Allergan Complaint) at ¶8.) In these nine other cases, Apotex Inc. engaged the services of Delaware law firms to represent it. (AZ Ex. 5 at 6-8).)

D. Apotex Inc.'s Commercial Activities in Delaware Through Its Agent Apotex Corp.

Apotex Corp. is incorporated in Delaware (D.I. 1.1, ¶ 7; AZ Ex. 14 (AI 000002-7)), with its primary place of business in Florida (AZ Ex. 3 at 6). Formally, it is a sister corporation to Apotex Inc., with both having a common ultimate parent. (AZ Ex. 14 (AI000001).) Apotex Corp. serves as Apotex Inc.'s marketing and sales agent, and its agent for ANDAs in the United States:

> Apotex Corp. is the United States marketing and sales affiliate for [Apotex, Inc.] Following FDA approval of an ANDA, [Apotex, Inc.] manufactures and supplies generic drug products to Apotex Corp., which then markets and sells those products to large wholesalers, warehousing chains, mail order organizations, and distributors in the United States. Apotex Corp. also acts as [Apotex, Inc.'s] U.S. agent for purposes of making regulatory submissions, including ANDAs, to the FDA.

(AZ Ex. 6 ¶ 6 (Apotex Inc. Complaint against Pfizer)[5]; AZ Ex. 3 at 7.) Likewise in the present case, Apotex Inc.'s ANDA, which instigated this suit, identifies Apotex Corp. as Apotex Inc.'s

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[5] The text of the Complaint quoted above refers to "Torpharm" rather than "Apotex Inc." (AZ Ex. 6 ¶ 6.) Paragraph 8 of the Complaint explains that "Torpharm" refers collectively to the three plaintiffs, Torpharm, Inc., Apotex Corp., and Apotex Inc. (AZ Ex. 6 ¶ 8.) The subsequent Federal Circuit decision in the case identifies Torpharm as a prior name for Apotex Inc.,stating

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"AUTHORIZED U.S. AGENT" for the ANDA and was signed by Apotex Corp.'s Manager of Regulatory Affairs. (AZ Ex. 15.) Apotex Inc.'s Paragraph IV notification letter to AstraZeneca similarly named Apotex Corp. as its agent for service of process for litigation resulting from that notification. (AZ Ex. 16 at 7.)

As Apotex Inc.'s agent, Apotex Corp. markets, offers for sale, and sells Apotex Inc.'s generic drugs throughout the United States, including in Delaware.[6]

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Apotex Corp. entered into contracts with Happy Harry's pharmacies in Delaware to distribute Apotex Inc.'s drug products. (AZ Ex. 4 (AC000001-4, 68-70, 78-81); AZ Ex. 17 at 3.) In 2003, 2004, and 2006, Apotex Corp. sales representatives visited Happy Harry's pharmacies once a year. (AZ Ex. 18.) For the remainder, Apotex Corp. actively tracks indirect sales of Apotex Inc.'s drug products to individual Delaware pharmacies through wholesalers and distributors. (AZ Ex. 4 (AC000066-73).)

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in its title: "Apotex Inc. (formerly known as Torpharm, Inc.)." (AZ Ex. 22.) In addition, Apotex Inc. stated that over the past five years, the product made by Apotex Inc. has been distributed in the United States by Apotex Corp. (AZ Ex. 17 at 1-2.)

[6] AZ Ex. 3 at 7; AZ Ex. H (Apotex Inc. Answer to Senju Complaint) at ¶6 (admitted that "Apotex Corp. offers for sale and sells drug products in the United States, including [Delaware], manufactured and supplied by Apotex Inc."); AZ Ex. 9 (Apotex Inc. Answer to Allergan Complaint) at ¶6 (admitted that "Apotex, Inc. [sic] manufactures numerous generic drugs for sale and use throughout the United States, including [Delaware]")); AZ Ex. 10 (Apotex Inc. Answer to MedPointe 2007 Complaint) at ¶6 (admitted that "Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in [Delaware]").

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Following FDA approval of its present ANDA, Apotex Inc. intends to sell its generic drugs through Apotex Corp. and its established distribution channels throughout the United States, including Delaware, as it intends in other ANDA cases. (D.I. 1.1 ¶ 28; AZ Ex. 10 (Apotex Inc. Answer to Medpointe 2007 Complaint) at ¶ 7 (admitted that "Apotex Inc. intends to sell generic product accused of infringement in this Complaint through Apotex Corp. throughout the United States following any FDA approval, unless there is Court intervention."); AZ Ex. 11 (Apotex Inc. Answer to Medpointe 2006 Complaint) at ¶¶ 6-7 (admitted that "following FDA approval of the proposed drug product, Apotex Inc. intends to supply Apotex Corp. with the proposed drug product for sale in the US," and "following FDA approval of the proposed drug product, Apotex Corp. intends to sell [the proposed drug product] in the U.S.").

IV. ARGUMENT

A. The Law of Personal Jurisdiction

When examining personal jurisdiction in the context of patent litigation, the law of the Federal Circuit applies. *See Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1358 (Fed. Cir. 1998). To decide whether personal jurisdiction exists over an out-of-state defendant, the Court must determine: (1) whether the forum state's long-arm statute permits service of process; and (2) whether the exercise of jurisdiction comports with due process. *See*

Genetic Implant Systems, Inc. v. Core-Vent Corp., 123 F.3d 1455, 1458 (Fed. Cir. 1997).

The Delaware long-arm statute has been construed "liberally so as to provide jurisdiction to the maximum extent possible" in order "to provide residents a means of redress against those not subject to personal service within the State." *Boone v. Oy Partek Ab,* 724 A.2d 1150, 1156-57 (Del. Super. Ct. 1997). It states, in relevant part:

> (c) As to a cause of action brought by any person arising from any of the acts enumerated in this section, a court may exercise personal jurisdiction over any nonresident, or a personal representative, who *in person or through an agent*: . . .
>
> (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State . . . .

10 Del. C. § 3104(c)(4) (emphasis added). AstraZeneca contends that this Court has general jurisdiction over Apotex Inc. based on its continuous and systematic general business contacts with Delaware. *See Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 414-16 (1984).

B. Personal Jurisdiction Over Apotex Inc. Is Proper

Personal jurisdiction exists over Apotex Inc. here because the Delaware long-arm statute permits the service of process and the exercise of jurisdiction comports with due process requirements.

1. Apotex Inc. Transacts Business in Delaware Through Its ANDA Litigation

a. ANDA Litigation Is a Regular Business Activity of Generic Drug Manufacturers Such as Apotex Inc.

Apotex, Inc. is one of the largest suppliers of generic drugs in the United States. Unlike other businesses where litigation is an occasional, unintended, and undesirable consequence of business activities, patent litigation is a regular and intended component of the ordinary business activities of companies seeking to sell their generic drug products in the United

States. This business activity is an outgrowth of the legislative scheme, the so-called "Hatch-Waxman Act,"[7] that regulates competitive activity between research-based pharmaceutical companies like AstraZeneca and generic drug companies like Apotex Inc.

The legislation contemplates that a research-based pharmaceutical company will conduct research and development to discover a new pharmaceutical product, seek to patent it, proceed to conduct lengthy and expensive human clinical trials to establish the safety and efficacy of the drug, and file a New Drug Application ("NDA") with the FDA. If approved, the innovator company will be given permission to market the new drug in the United States.

The Federal Circuit has described the Hatch-Waxman Act and the ANDA litigation procedure in *Andrx Pharms.*, 276 F.3d at 1370-71, and *Mylan Pharms.*, 268 F.3d at1325-27. As explained there, under the statute, a generic drug manufacturer is permitted to seek FDA approval to market a generic copy of an innovator's FDA-approved new drug without submitting results of its own long and expensive clinical testing of the innovator's product. The generic drug company must simply show that its proposed generic copy is bioequivalent, which generally means that the copy contains the same active substance, it will be given to patients in the same dosage form, and it will provide the same levels of active ingredient in the blood as the approved product. The generic manufacturer is allowed under statutory "safe-harbor" provisions to use the innovator's patented product in testing to generate data for FDA-submission. 35 U.S.C. § 271(e)(1).

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[7] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified at* 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

The generic drug maker may file an ANDA containing bioequivalence data to seek FDA permission to market the generic copy upon expiration of the innovator's patent. A generic drug manufacturer may also seek FDA approval to market a generic copy of an approved, patented drug *prior* to expiration of all patents covering the drug. If the generic drug manufacturer seeks permission to market the generic copy *before* patent expiration, it may do so by certifying to the FDA that it will not infringe any valid and enforceable claim of the innovator's patent (a so-called "Paragraph IV" certification) and thereafter notifying the patent owner as required by the enabling regulations. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If, after receiving the Paragraph IV certification notice, the patent owner files suit for infringement within 45 days, the statute imposes an automatic 30-month stay of FDA approval of the ANDA to allow the court to resolve the patent issues. 21 U.S.C. § 355(j)(5)(B)(iii).

Lucrative rewards await generic drug companies making Paragraph IV certifications, and the companies have strong financial incentives to submit ANDAs having them. The reason is straightforward. Under the statute, the *first* generic drug manufacturer to file an ANDA having a Paragraph IV challenge is awarded 180 days of generic marketing exclusivity if the challenge is successful and the generic product is launched prior to the expiration of the patent. 21 U.S.C. § 355(j)(5)(B)(iv).

The practice that has grown up under this legislative scheme is one where the patent on virtually every important new pharmaceutical product is challenged by one or more generic drug companies racing to the FDA to file ANDAs having Paragraph IV certifications and actively litigating the patent validity, enforceability, and infringement issues in federal district court. Thus, whereas innovators like AstraZeneca gain access to new products through business activities conducted in the laboratory related to product development, generic drug makers like

Apotex Inc. gain access to new products through business activities regularly, systematically, and foreseeably conducted in federal court.

The federal district court in Delaware is no stranger to this type of litigation. Indeed, this Court has become a favored forum for this kind of litigation for plaintiffs and defendants alike. The preference arises from the historical reputation of judges in this district for excellence and sophistication in patent matters and this district's practice of bringing these matters to trial well before expiration of the 30-month stay of FDA approval (reflected in the February 2010 trial date set in this case). Not surprisingly, therefore, many generic drug companies that could challenge personal jurisdiction in this district choose instead to purposefully avail themselves of the benefits of litigating ANDA cases in Delaware by voluntarily appearing here and even filing counterclaims here.

Both Apotex Inc. and Aurobindo Pharma Ltd. have engaged in this activity in this district. Both are thus engaged in a regular component of their generic drug business—ANDA litigation—here in Delaware, and both should, therefore, be found to be generally present in this district.

b. Apotex Inc. Is Conducting Its ANDA Litigation Business in Delaware

Apotex's actual litigation decisions, public statements, and activities in Delaware courts—all advancing its business interests by engaging in ANDA litigation—amply illustrate the point. The filing of ANDAs with Paragraph IV certifications challenging patents and the resultant federal court litigation is a key part of Apotex Inc.'s regular business activities.

As Apotex Inc.'s Chairman and Chief Executive Officer, Dr. Bernard Sherman, testified during a hearing before a committee of the U.S. House of Representatives:

> At Apotex, we believe generic companies should endeavor to bring generics to market at the earliest possible time, and that the legislative and regulatory

> framework should facilitate, not obstruct, early generic entry. Our record in advocating for such a public policy framework, from our support for a district court trigger for exclusivity rather than an appellate trigger, *our pursuit of declaratory judgment actions*, our efforts in the courts to vacate anti-competitive settlements, *our pursuit of infringement verdicts even where there is no guaranteed benefit to us*, and our opposition to patent settlements, is unique and unmatched among generic manufacturers.
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> Year after year, Apotex has tirelessly litigated to bring products to market . . . .

(AZ Ex. 19 (*Protecting Consumer Access to Generic Drugs Act of 2007:Hearings on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the House Comm. on Energy and Commerce*, 110th Cong. (May 2, 2007) (statement of Barry Sherman, Chief Executive Officer of Apotex Inc.) 2007 WL 1290291, at *1-2, 5. (emphasis added)).) As a 2002 published article observed:

> In a single word: litigation. Apotex is famous for suing anybody who tries to stop it selling [sic] a generic version of a bestselling drug. No matter that the inventors' patents may have years to run; Mr. Sherman is a master at picking holes in such claims, and then pursuing his interests in court. His company is embroiled in almost 100 lawsuits and spends more than $10m a year in legal fees.

(AZ Ex. 20 (*Barry Sherman and His Generic-Drug Company, Apotex, Have Put Big Pharma in a Tizzy*, Economist (April 11, 2002).)

In just the past five years, Apotex Inc. has been a party to over 60 patent suits in the United States. (AZ Ex. 21.) Nine of those other suits also were filed in Delaware. (AZ Ex. 5 at 6-8.) In one, Apotex Inc. was the plaintiff in a declaratory judgment suit, in which Apotex Inc. sued Pfizer. (AZ Ex. 6.) As a result, Apotex Inc. obtained a covenant not to sue and began selling a generic version of the pharmaceutical product at issue in that case, quinapril. (*Id.*; AZ Ex. 22 (Fed. Cir. decision noting covenant not to sue); AZ Ex. 3 at 8.)

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In seven of the remaining Delaware cases (the eighth was dismissed before the Answer was filed), Apotex Inc. answered the Complaints, raised Counterclaims, and never challenged personal jurisdiction. (AZ Exs. 7 - 13 (Answers to Delaware Complaints).) In February of this year, while simultaneously contesting this Court's jurisdiction over it, Apotex Inc. again consented to personal jurisdiction in Delaware. (AZ Ex. 12.)

Quite significantly, less than a year ago, Apotex Inc. unequivocally admitted the propriety of personal jurisdiction over it in Delaware in an ANDA case indistinguishable from this one:

> 8. Based on the facts and causes alleged herein, this Court has personal jurisdiction over Defendants.
>
> ANSWER: Admitted that the Court has personal jurisdiction over Apotex Inc. and Apotex Corp.; otherwise denied.

(AZ Ex. 9 (Apotex Inc. Answer to Allergan Complaint) at ¶8.)[8]

In those nine other cases, Apotex Inc. engaged the services of Delaware law firms to represent it and presumably paid the law firms substantial sums. (AZ Ex. 5 at 6-8.)

Because Apotex Inc. actively conducts its ANDA litigation business in Delaware, and avails itself of the resources of the Delaware courts to advance its business purposes, it is amenable to service of process under the Delaware long-arm statute. *See, e.g., Colonial Mortgage Serv. Co. v. Aerenson,* 603 F. Supp. 323, 325, 327 (D. Del. 1985) (general jurisdiction held to exist where, *inter alia*, the defendant had "repeatedly invoked the benefits of the Delaware state courts to protect its interests" by filing suit in Delaware). In addition, because Apotex Inc. has demonstrated through its voluntary presence in the federal district court in

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[8] The only apparent distinction between the Delaware cases in which Apotex Inc. did not challenge jurisdiction and this case where it has challenged jurisdiction is the identity of the judges to whom the cases were assigned.

Delaware that it could reasonably expect to be haled into court here and can, without undue burden, appear here and defend itself, the exercise of personal jurisdiction over Apotex Inc. comports with due process.

2. Apotex Inc. Transacts Business in Delaware Through Its Delaware Agent

Apotex Inc. well satisfies Delaware's long-arm statute, because "in person or *through an agent*" it not only "does . . . business," but also "engages in [a] persistent course of conduct in the State" and "derives substantial revenue from services, or things used or consumed in the State." 10 Del. C. § 3104(c)(4) (emphasis added).

Apotex Inc. employs a Delaware corporation, Apotex Corp., as its agent for its ANDA filings, including the ANDA triggering the litigation here. Apotex Inc. also employs that Delaware corporation as its agent for marketing and selling its generic drugs in Delaware and the rest of the United States,

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In addition, through that Delaware agent, Apotex Inc. tracks those sales to the Delaware pharmacies in which Apotex Inc.'s generic drugs are sold to Delaware consumers. Through that agent's sales representatives, it also has visited its direct customer in Delaware, Happy Harry's pharmacies. The fact that Apotex Inc. sold a portion of its products through independent wholesalers and distributors rather than directly to pharmacies in Delaware is not material. *See Eli Lilly and Co. v. Mayne Pharma (USA) Inc.*, 504 F. Supp. 2d 387, 394 (S.D. Ind. 2007). As in *Eli Lilly*, the presence of middlemen does not change the systematic contacts with Delaware,

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See id.

Apotex Inc. argues that it "does not have any subsidiaries located in Delaware . . . ." (Apotex Br. at 5.) The Apotex Group, however, which Apotex Inc. heads, incorporated Apotex Corp. in Delaware and obtains the benefits of that incorporation, despite locating Apotex Corp.'s facilities in Florida.

In cases involving a non-resident defendant, the scope of the long-arm statute has been analyzed under an agency theory. For example, in *Wesley-Jessen Corp. v. Pilkington Visioncare, Inc.*, 863 F. Supp. 186 (D. Del. 1993), personal jurisdiction over a non-resident was found based on an agency theory. There, as here, two corporate defendants were members of the same corporate group, were indirectly wholly-owned by the same ultimate corporate parent, and one argued that no personal jurisdiction existed over it. *Id.* at 187. As the court explained, "an agency relationship may exist between corporate affiliates with close business ties," and "[i]f an agency relationship existed between the two companies, then [the defendant] is amenable to suit in Delaware." *Id.* at 188. As here, the defendant challenging jurisdiction argued that it was shielded from jurisdiction because the "tasks of manufacturing and distributing the product were divided between independent corporations." *Id.* The court rejected there as "not relevant" the argument that the "group chooses to divide tasks" between the defendants. *Id.* at 189. Quoting from a similar case in another district, it explained:

> Regie [a French corporation] might choose to arrange its marketing process through a hierarchy of its own agents and employees. Then, by establishing agents in California to sell its products, it would undoubtedly be amenable to suit in this state. For reasons of its own it chooses to market its products through a wholly-owned American subsidiary and a network of independently-owned distributorships and dealerships. These choices on its part effect little, if any, alteration in the jurisdictional situation. The "contacts" exist one way or the other and for precisely the same purpose. The differences are differences only in form and description.

Id. at 189 (*quoting Regie Nationale Des Usines Renault v. Superior Court,* 208 Cal. App. 2d 702 (Cal. App. 1962)). Applying that rationale, the court found personal jurisdiction based on the

two affiliated corporations being "considered two arms of the same business group in their attempt to achieve the common goal of selling [products] in Delaware and other markets." *Wesley-Jessen,* 863 F. Supp. at 189. The court further rejected as irrelevant the argument that the companies were not related as parent-subsidiary, finding that "[i]t is enough that both . . . are wholly owned affiliates of" the same ultimate corporate parent.

Like the defendant in *Wesley-Jessen*, Apotex Inc. attempts to shield itself from personal jurisdiction by manufacturing its generic products in Canada, while employing Apotex Corp. as its agent to market and distribute Apotex Inc.'s products to wholesalers, distributors, and pharmacies in the United States, including for ultimate distribution and use in Delaware. *See id.*, 863 F. Supp. at 188. Likewise, that relationship has resulted in substantial sales in the United States, including Delaware. Like the related entities in *Wesley-Jessen*, Apotex Inc. and Apotex Corp. are two parts of the Apotex Group, which Apotex Inc. heads, that attempt to achieve their common goal of selling Apotex Inc.'s products in Delaware and elsewhere. *See id.* at 189. Accordingly, Apotex Inc. has systematic and continuous contacts in Delaware both through its own actions and that of its agent, Apotex Corp., a Delaware corporation, justifying a finding of general jurisdiction.

Apotex Inc. inappositely relies on *Merck & Co. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368 (D. Del. 2002), ignoring several major distinctions with the case at bar. First, the business of ANDA patent litigation is at the core of Apotex Inc.'s exportation of generic drugs to the United States, and Apotex Inc. performs a substantial amount of that litigation in Delaware, including initiating litigation and filing counterclaims. In doing so, Apotex Inc. purposefully avails itself of the benefits of courts in this district and the services of Delaware attorneys, as it did in at least eight other contested cases in the last five years alone. Such very significant Delaware activities

apparently did not exist in the *Merck* case, for the Court did not mention them in its opinion. Indeed, the Court found that the defendant there had "not availed itself of Delaware resources." 179 F. Supp. 2d at 375.

Second, Apotex Inc. employs its agent, a Delaware corporation, to file its ANDA in this and other ANDA cases, and to market and sell its generic drugs in Delaware and the United States for the Apotex Group. Those contacts include: (1) the established distribution networks that bring Apotex Inc.'s generic drugs into Delaware;

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(4) the visits to Happy Harry's pharmacies by sales representatives. These repeated forum activities and the resulting benefits to Apotex Inc. differ greatly from the single contract with an unrelated Delaware corporation to store and distribute one unrelated product for a limited time, which the Court in *Merck* found did not make the distributor an agent. 179 F. Supp. 2d at 371, 373. In addition, unlike here, the Court found that the defendant there did not solicit business in Delaware. *Id.* at 375.

Third, in *Merck*, the defendant's Delaware revenues comprised less than 0.13% of Barr's total revenue, which the Court found was not substantial enough to warrant exercise of general jurisdiction. *Id.* at 373. While Apotex Inc. may argue that

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AZ Ex. 23 (U.S. Census Bureau website (2006 data): Del. 853,476; USA 299,398,484; percentage 0.285%).) Moreover, unlike *Merck*, many more contacts between Apotex Inc. and Delaware exist, and

jurisdiction is not premised on those sales alone. *See Wright v. American Home Products Corp.*, 768 A.2d 518, 530 (Del. Super. Ct. 2000) (finding specific and general jurisdiction where, even though 22,191 Delaware prescriptions paled in significance to 11,584,797 nationwide prescriptions, the court found "a clear pattern of repeated activity in this State [Delaware]").

The Federal Circuit has held that several millions of dollars of sales per year of products in the forum state, along with a distributorship network, support general jurisdiction. *See LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1375 (Fed. Cir. 2000). That defendant employed "multiple distributors in Ohio and nets several millions of dollars per year from sales in Ohio," which the Federal Circuit held constituted "maintain[ing] 'continuous and systematic' contacts" with Ohio. *Id.*, 232 F.3d at 1375.

Whether the amount of income derived from the forum state is a small portion of the defendant's total income "is not decisive." *Hill v. Equitable Trust Co.*, 562 F. Supp. 1324, 1331 (D. Del. 1983). "Generally speaking, the appropriate inquiry under Section 3104(c)(4) is whether [the defendant], in absolute dollar amounts, 'derives substantial revenue' from Delaware." *Id.* Moreover, even if the "revenue derived from Delaware is insubstantial, Section 3104(c) provides for jurisdiction if the defendant's conduct is persistent or regular in Delaware, irrespective of the substantiality of the revenue derived from the State." *Id.* Accordingly, the *Hill* court found personal jurisdiction existed even though the defendant's income from transactions in Delaware amounted to only about $50,000. *Id.* Likewise, a recent ANDA case found general jurisdiction existed where the defendant's sales in the forum state over four years totaled $6 million. *See Eli Lilly*, 504 F. Supp. 2d at 390-91.

As the court recognized in *Eli Lilly*, "[i]t is the nature of the activity, rather than its quantitative character, that must be analyzed to determine whether the court has personal

jurisdiction." *Id.* at 395 (cited source omitted). Here, Apotex Inc. has directed its continuous and systematic business activities of litigating ANDAs and selling its products in Delaware.

Fourth, unlike *Merck*, this case involves a Delaware plaintiff—AstraZeneca Pharmaceuticals—and "Delaware has a strong preference in favor of affording its citizens, such as a Delaware resident in this case, a judicial forum and respecting their choice of forum." *Wright*, 768 A.2d at 539; *cf. Merck*, 179 F. Supp. 2d at 375 (stating that the case did not involve Delaware plaintiffs as a factor in concluding that Delaware has no interest in adjudicating the case).

Apotex also cites *Zeneca Ltd. v. Mylan Pharms., Inc.*, No. S 96-1746, 1997 U.S. Dist. LEXIS 12377, at *7-8 (D. Md. Jan. 3, 1997), and *Glaxo Wellcome Inc. v. Mylan Pharms., Inc.*, Civ. No. AMD 96-3477, 1997 U.S. Dist. LEXIS 23930, at *6-7 (D. Md. March 31, 1997), which present factual situations similar to that in *Merck*. Those cases, as well, lack the additional factors present here and likewise are distinguishable. Apotex Inc. also inappositely relies upon *Glaxo Inc. v. Genpharm Pharms., Inc.*, 796 F. Supp. 872, 875-76 (E.D.N.C. 1992), where the sole contact with the state, North Carolina, was the mailing of an ANDA certification to an address in that state. In contrast, Apotex, Inc. has many more and continuous contacts with Delaware.

3. Due Process Is Satisfied

As this Court has recognized, "[d]ue process requires that a defendant have certain minimum contacts with the forum state in order to ensure that the maintenance of the lawsuit does not offend 'traditional notions of fair play and substantial justice.'" *Merck*, 179 F. Supp. 2d at 375, *citing Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). "[T]o maintain general jurisdiction over a foreign defendant, the facts must establish 'continuous and systematic general business contacts' with the forum state." *Merck*, 179 F. Supp. 2d at 375, *citing Helicoperos*, 466

U.S. at 416. Where minimum contacts are found, the Court must consider whether "it would be unreasonable for the forum to assert jurisdiction under all the facts and circumstances . . . ." *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568 (Fed. Cir. 1994). However, "[i]n general, these cases are limited to the rare situation in which the plaintiff's interest and the state's interest in adjudicating the dispute in the forum are so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum." *Id.*

AstraZeneca contends that Apotex Inc. is subject to the general jurisdiction of this Court, not specific jurisdiction. To meet the due process standard, AstraZeneca need not demonstrate, as Apotex Inc. wrongly argues, that Apotex must have "purposefully directed [its] activities at the forum state," and that the present litigation "arises out of" or "relates to" those activities. (Apotex Br. at 8.) Apotex Inc.'s truncated quote from the Supreme Court in its brief omits the key qualifier, namely that such analysis is not applicable to general jurisdiction, but rather "[w]here a forum seeks to assert *specific jurisdiction* over an out-of-state defendant who has not consented to suit there." *Burger King Corp v. Rudzewicz*, 471 U.S. 462, 472 (1985) (emphasis added); *Breckenridge Pharm., Inc. v. Metabolite Labs., Inc.*, 444 F.3d 1356, 1361 (Fed. Cir. 2006) ("Where a defendant is not subject to general jurisdiction in the forum state, a district court may nonetheless exercise specific jurisdiction over the defendant if the cause of action 'arises out of' or 'relates to' the defendant's in-state activity.")

The facts discussed above demonstrate that Apotex Inc. has continuous and systematic business contacts, and even purposefully avails itself of the privilege of doing business in Delaware through its litigation as a plaintiff and as a defendant with counterclaims, and its sales of its generic drugs through its Delaware corporation agent, Apotex Corp. *See Wesley-Jessen*, 863 F. Supp. at 190 (finding due process satisfied where foreign defendant made sales of

products outside Delaware knowing that they would be sold by its related company "in other states across the nation, including Delaware.")

As is obvious, Apotex Inc. never contested personal jurisdiction in Delaware in its eight other contested cases in the last five years. Indeed, in answering a Complaint in an ANDA action less than a year ago, Apotex Inc. "[a]dmitted that the Court has personal jurisdiction over Apotex Inc. . . . ." (AZ Ex. 9 (Allergan Answer) at ¶ 8.) This admission by a sophisticated litigant in a directly analogous circumstance is strong evidence that Apotex Inc. fully expects or should fully expect to be sued in ANDA cases in the District of Delaware.[9] Given Apotex Inc.'s multiple litigations in Delaware in which it has not contested jurisdiction, has asserted counterclaims, and has asserted a declaratory judgment claim, it could well expect to be haled into court in Delaware. *See Wesley-Jessen*, 863 F. Supp. at 190. These significant forum related activities flatly contradict Apotex Inc.'s new claim that personal jurisdiction would violate due process.

Apotex Inc. argues that it has not had "continuous or systematic contact that would meet the strict requirements of due process," relying on *Merck*. (Apotex Br. at 8.) The same reasons that the facts in *Merck* are distinguishable discussed above apply here, as well.

This is far from those rare situations where AstraZeneca's and the state's interest are clearly outweighed by the burden of subjecting Apotex Inc. to litigation in this district. *See Beverly Hills Fan*, 21 F.3d at 1568. AstraZeneca's and Delaware's interests in adjudicating this

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[9] Finding personal jurisdiction here also comports with time-honored precedent. *See Pope v. Allis*, 115 U.S. 363, 370 (1885) ("When a bill or answer in equity or a pleading in an action at law is sworn to by the party, it is competent evidence against him in *another* suit as a solemn admission by him of the truth of the facts stated." (emphasis added)).

dispute are aligned. "Delaware has an interest in discouraging injuries that occur within the state, which extends to patent infringement actions such as the one here." *Energy Transp. Group, Inc. v. William Demant Holdings A/S*, C.A. 05-422 GMS, 2008 WL 78748, at *5 (D. Del. Jan. 4, 2008); *cf. Merck*, 179 F. Supp. 2d at 375 ("This case does not involve Delaware related claims or Delaware plaintiffs."). In addition, given its multiple Delaware litigations, Apotex Inc. can hardly allege a significant burden in litigating here.

4. If Personal Jurisdiction Were Found To Be Lacking, the Action Against Apotex Inc. Should Be Transferred Rather than Dismissed

If this Court were to find a lack of personal jurisdiction over Apotex Inc., it should transfer the portion of the action against Apotex Inc. to the Middle District of Florida, as Apotex Inc. alternatively requests, rather than dismiss.[10] As Apotex Inc. points out, when a court determines that personal jurisdiction over the ANDA filer does not exist, it commonly transfers the action rather than dismissing it. (Apotex Br. at 9.)

Such transfer would be particularly important here to protect AstraZeneca from possibly losing important rights provided by the Hatch-Waxman statute. Although never decided in a reported decision, dismissing an ANDA action after the 45-day lawsuit initiation period has expired might raise a question as to whether the 30-month FDA stay of approval remains, because it is unclear whether a dismissed suit is considered filed for purposes of the statute. *See Abbott Labs. v. Mylan Pharms., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (March 28, 2006) (recognizing that 21 U.S.C. 355(j)(5)(B)(iii) is silent, and courts have not clarified, whether the

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[10] Even if this Court were to conclude that it lacks personal jurisdiction over Apotex Inc., it unquestionably has personal jurisdiction over the actual signer of the ANDA that instigated this action—Apotex Corp.—which is a Delaware corporation. It also has subject matter jurisdiction, as explained in Plaintiffs' Opposition to Apotex Corp.'s Motion to Dismiss for alleged lack of subject matter jurisdiction. (D.I. 28.)

patent holder loses its right to sue for patent infringement and maintain its 30-month FDA stay in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired).

Dismissing this case and possibly jeopardizing AstraZeneca's right to a 30-month stay of FDA approval of this ANDA would be harsh and entirely unjustified, especially given AstraZeneca's reasonable reliance on Apotex Inc.'s prior admission that it was subject to jurisdiction in this district and its systematic contacts with this forum. AstraZeneca took steps to file protective suits in other districts where there appeared to be a possibility of a jurisdictional challenge. It did not do so here based on Apotex Inc.'s history of litigation in this district. It would be a miscarriage of justice to allow Apotex Inc. to profit from a completely unforeseeable abandonment of its prior admission by allowing it to secure dismissal rather than transfer of this action.

V. CONCLUSION

For the foregoing reasons, the Court should deny Apotex Inc.'s motion to dismiss for alleged lack of personal jurisdiction.

This 21st day of April 2008.
Redacted Version Filed: April 28, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, hereby certify on this 28th day of April, 2008 I electronically filed the foregoing Redacted Version of PLAINTIFFS' OPPOSITION TO DEFENDANT APOTEX INC.'S RULE 12(b)(2) MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION, OR IN THE ALTERNATIVE TO TRANSFER TO THE MIDDLE DISTRICT OF FLORIDA with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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